REMARKS/ARGUMENTS

By the *Office Action* of 24 November 2009, Claims 1-44 and 46-54 are pending in the *Application*, Claims 12, 13, 39-44, and 46-48 are withdrawn from consideration, and Claims 1-11, 14-38, and 49-54 are rejected. Applicant thanks the Examiner with appreciation for the careful consideration and examination given to the *Application*.

Applicant submits this *Response and Amendment* solely to facilitate prosecution. As such, Applicant reserves the right to pursue claims of broader or similar scope as originally filed in a continuation application or other application after allowance of the present *Application*. Applicant does not concede that the current or past rejections are correct and reserves the right to challenge such rejections later in prosecution or on appeal. Accordingly, any amendment, argument, or claim cancellation is not to be construed as abandonment or disclaimer of subject matter. As certain of the current amendments may include broadening amendments, Applicant respectfully requests the Examiner to revisit any previously reviewed references cited in this *Application* to further ensure that the currently pending claims remain patentable over any previously reviewed references.

By the present *Response and Amendment*, Claim 1 is amended, and Claims 2-3 and 14-15 are cancelled. No new matter is believed presented, and all pending Claims are believed allowable. With regard to written support in the present *Application*, all references herein are to paragraph numbers with respect to the published *Application*.

1. The Present Invention

The present *Application* discloses a cosmetic formulation that comprises a hydroalcoholic gel dispersion containing: the insoluble salicylic acid; a gelling agent in the form of a copolymer of acryloyl dimethyl tauric acid or a salt thereof and another vinyl monomer; and water in excess of 50% w/w of the dispersion. Therefore, the present invention is directed to a hydroalcoholic gel dispersion where water is the major solvent and the alcohol is present in an amount less than the aqueous content. This hydroalcoholic gel dispersion is stable at a pH of about 3 to about 6.

The hydroalcoholic gel dispersion of the present invention overcomes a major hurdle in the formulation of salicylic acid containing gels at relatively low pH. It is known problem in the

field that "many gelling agents do not form effective gels at low pH to form a cosmetically acceptable hydroalcoholic gel which solubilizes salicylic acid adequately. . . . Furthermore, gelling agents useful at low pH may not function adequately in hydroalcoholic systems as the alcohol changes the solvation characteristics of the polymer in the aqueous system." (Applicant's *Specification*, ¶ 7)

The stable hydroalcoholic gel dispersion of the present *Application* has a sufficiently high viscosity (e.g., a range of about 50 mPa·s to about 20,000 mPa·s) to facilitate handling and dispensing of the composition, but is capable of flowing freely and being readily spreadable when applied to the intended site of application. In addition, the hydroalcoholic gel is suitable for application to the skin to treat damaged skin, such as acne.

2. Support for the Clarified Claims Can Be Found in the Originally-Filed Application

Support for clarified Claim 1 can be found in at least ¶¶ 8, 30, 33, 38, and 78 and Claims 2, 11, and 15 as originally filed.

3. The Amendments to the *Specification* Are Not New Matter

The amendments to the *Specification* are made to comply with the guidelines for the preferred layout of the *Specification* under 37 CFR § 1.77(b). Applicant submits that the *Specification*, as amended, includes no new matter.

4. Rejection of Claims 1-11, 14-29, and 38 under 35 U.S.C. § 103(a)

The Examiner rejected Claims 1-11, 14-29, and 38 under 35 U.S.C. § 103(a) as allegedly being unpatentable over U.S. Patent No. 6,428,772 to Singh *et al.* ("Singh"), a publication by Singh and Roberts in *JPET* ("Singh & Roberts"), International Publication No. WO 99/39713 to Hong *et al.* ("Hong"), a publication by Obata *et al.* in *Int. J. Pharm.* ("Obata"), and a publication by Loffler *et al.* in *HAPPI* ("Loffler"). The Examiner stated that "it would have been obvious to a person of ordinary skill in the art at the time the invention was made to formulate a skincare composition comprising the NSAID salicylic acid in the form of a hydroalcoholic gel dispersion. The skilled artisan would have been motivated to do [this] in view of *Singh and Roberts* – which teach that topical formulations of NSAIDs show low skin permeability – and in view of *Hong et al.* which specifically teach that hydroalcoholic formulations comprising piroxicam decrease the

external loss of the NSAID and increase the permeation of the NSAID through the skin." (*Office Action*, ¶ 10). The Examiner further stated that "in view of *Obata et al.*, which demonstrate that ethanol enhances skin permeation of the NSAID diclofenac by attacking the dense barrier structure of the skin, the skilled artisan would have reasonably predicted that the hydroalcoholic gel dispersion taught by *Hong et al.* enhances piroxicam permeability by disrupting the skin barrier, a condition which would similarly enhance the permeation of salicylic acid." (*Office Action*, ¶ 10). The Examiner concluded that "it would have been obvious to a person of ordinary skill in the art to formulate the hydroalcoholic gel dispersion taught by *Hong et al.* using Aristoflex AVC as the gelling agent[, as described in *Loffler et al.*]." (*Office Action*, ¶ 12).

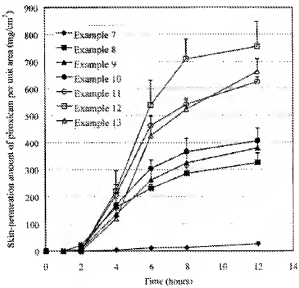
To provide a rejection for obviousness, the Examiner has the initial burden to at least determine the scope and content of the prior art and to ascertain the differences between the prior art and the claims at issue under the respective first and second factual inquiries of *Graham v. John Deere Co.*, 383 US 1 (1966). In view of the clarified claims, Applicant respectfully submits that the Examiner no longer meets the initial burden of determining the scope and content of the prior art and ascertaining the differences between the prior art and the claims at issue. Therefore, Applicant respectfully traverses this rejection.

Applicant submits that pending clarified claims recite a limitation that the hydroalcoholic gel dispersion comprises water in excess of 50% w/w. Singh, Singh & Roberts, Hong, Obata, and Loffler, either individually or combined, do not teach or suggest a hydroalcoholic gel dispersion comprising salicylic acid or a salt thereof where the amount of water in the composition is in excess of 50% w/w. In fact, Hong, Obata, and Loffler expressly teach away from the claimed invention and the use of a hydroalcoholic gel containing in excess of 50% w/w water.

Although Hong discloses that hydroalcoholic gel systems may be used to increase the permeation of piroxicam through the skin, it is a requirement of such systems that a C_{1-4} alkanol provides the main solvent. (Hong, p. 4, ll. 16-17). Hong expressly teaches that the amount of the lower alcohol is 1-3 times that of the amount of water used. (Hong, p. 4, ll. 20-22). Hong discloses that the use of the lower alcohol as a main solvent is required to form a film on the skin surface without drug precipitation or polymer aggregation (Hong, p. 4, ll. 20-22). Accordingly, Applicant submits that it would not have been *prima facie* obvious to formulate the Hong

hydroalcoholic gel composition with greater than 50% w/w water, (i.e., to use the alcohol in a minor proportion relative to the amount of water) as there is an absence of a reasonable expectation of success of the formation of a satisfactory hydroalcoholic gel product.

In fact, Hong expressly teaches away from the use of a hydroalcoholic gel where water is present in an amount in excess of 50% w/w water. Hong provides only one example (Example 7) where the amount of water (53.2% w/w) exceeds the amount of ethanol (30% w/w). (Hong, Table 7, p. 15). Of all of the examples disclosed by Hong, Example 7 demonstrates the lowest skin permeation profile, as shown to the right in Figure 1 of Hong. If the water content is decreased from 53.2% w/w to 38.2% w/w (Example 8), there is a **700%** increase in the permeation of piroxicam. Based on this data, Hong expressly teaches that a hydroalcoholic gel containing in excess of 50% w/w water is not effective. Therefore, Hong expressly teaches away from the claimed invention and the use of a hydroalcoholic gel containing in excess of 50% w/w water. Based on the teachings of Hong, a person of ordinary skill in the art would not have a reasonable expectation of success in forming an effective hydroalcoholic gel containing in excess of 50% w/w water.



Similarly, Obata teaches that a high alcohol content is necessary to achieve the permeability of drugs through the skin. Obata concludes that "a *large amount of ethanol* may increase the permeation of drugs through the lipid pathway by affecting the dense barrier structure of the skin." (Obata, p. 198, col. 1, ll. 37-40, *emphasis added*). Also, Obata acknowledges an earlier disclosure that teaches '[t]he maximum permeability of salicylate ion was observed when *63% ethanol* was formulated in the donor solution." (Obata, p. 198, col. 1, ll. 19-21, *emphasis added*).

In view of these teachings, Obata expressly teaches away from the claimed invention and the use of a hydroalcoholic gel containing in excess of 50% w/w water. Considering that Obata teaches that large amounts of alcohol (e.g., 63%) are necessary to achieve permeability of salicylic acid through the skin, a person of ordinary skill in the art would not have a reasonable expectation of success in formulating a hydroalcoholic gel composition with greater than 50% w/w water (i.e., the amount of alcohol is a minor proportion relative to the amount of water).

With regards to the Loffler reference, Loffler discloses the stabilization of oil-in-water emulsions using the Aristoflex AVC copolymer. Loffler acknowledges that "[c]ompatibility with polar organic solvents is of interest for the formulation of hydro-alcoholic gel. Aristoflex AVC has good compatibility with polar organic solvents such as ethanol or acetone." (Loffler, p. 2, ¶ 3). Loffler, however, provides no further details concerning the formulation of hydroalcoholic gels with Aristoflex AVC.

Applicant respectfully submits that further details regarding the Aristoflex AVC copolymer are readily accessible to the person of skill in the art via the manufacturer's data sheet supplied by Clariant. This reference, *Aristoflex (R) AVC product data, January 2001*, ("Aristoflex AVC Data Sheet") was submitted for consideration in Applicant's *Information Disclosure Statement* of 18 August 2009. In the last paragraph of page 3, the Aristoflex AVC Data Sheet states that "Aristoflex AVC has a good compatibility with other polar organic solvents. Hydro-alcoholic transparent gels can be made comprising *more than 50% ethanol*." (Aristoflex AVC Data Sheet, p. 3, ¶ 4, *emphasis added*).

Similarly, another data sheet supplied by the manufacturer, Clariant, submitted in the same *Information Disclosure Statement* of 18 August 2009 under the reference *Aristoflex (R) HMB product data* ("Aristoflex HMB Data Sheet") also refers to the Aristoflex AVC and HMB polymers. In the last paragraph of page 2, the Aristoflex HMB Data Sheet states, "Aristoflex (R) polymers have a good compatibility with other polar organic solvents. Hydro-alcoholic gels can be made comprising *more than 50% ethanol*." (Aristoflex HMB Data Sheet, p. 2, ¶ 4, *emphasis added*).

Therefore, Applicant respectfully submits that a person of ordinary skill in the art after reading Loffler would access the above-referenced product literature. In doing so, a person of ordinary skill in the art would be motivated to only prepare hydroalcoholic gels with these

Aristoflex gelling systems using more than 50% ethanol. Therefore, Loffler, when read in its complete context in view of the Clariant product data sheets, expressly teaches away from the claimed invention and the use of a hydroalcoholic gel containing in excess of 50% w/w water. Consequently, a person of ordinary skill in the art would not have a reasonable expectation of success in forming an effective hydroalcoholic gel containing in excess of 50% w/w water in view of the teachings of Loffler.

Applicant submits that Hong, Obata, and Loffler, either individually or combined, do not teach or suggest a hydroalcoholic gel dispersion comprising salicylic acid or a salt thereof where the amount of water in the composition is in excess of 50% w/w. In fact, Hong, Obata, and Loffler expressly teach away from the claimed invention and the use of a hydroalcoholic gel containing in excess of 50% w/w water. Considering that each of Hong, Obata, and Loffler teach away from a hydroalcoholic gel containing in excess of 50% w/w water, Hong, Obata, and Loffler cannot render the clarified claims obvious.

The teachings of Singh and Singh & Roberts do not cure the deficiencies of Hong, Obata, and Loffler. The Examiner relies on Singh for teaching that "salicylic acid is sparingly soluble in water[, and Singh & Roberts teach] that salicylic acid and other NSAIDs (such as piroxicam and diclofenac) show low skin permeability when topically applied." (*Office Action*, ¶ 14 (2)). Neither Singh nor Singh & Roberts teach or suggest a hydroalcoholic gel dispersion comprising salicylic acid or a salt thereof where the amount of water in the composition is in excess of 50% w/w. As a result, Applicant respectfully requests the Examiner to withdraw this rejection.

5. Rejection of Claims 7-11, 14-24, 26-29, and 38 under 35 U.S.C. § 103(a)

The Examiner rejected Claims 7-11, 14-24, 26-29, and 38 under 35 U.S.C. § 103(a) as allegedly being unpatentable over Singh, Singh & Roberts, Hong, Obata, and Loffler. Claims 7-11, 14-24, 26-29, and 38 ultimately depend from, and include every element of, Claim 1. Thus, Claims 7-11, 14-24, 26-29, and 38 have been clarified to recite a limitation that the hydroalcoholic gel dispersion comprises water in excess of 50% w/w. For at least the reasons discussed above, Singh, Singh & Roberts, Hong, Obata, and Loffler, either individually or combined, do not teach or suggest a hydroalcoholic gel dispersion comprising salicylic acid or a salt thereof where the amount of water in the composition is in excess of 50% w/w. In fact, Hong, Obata, and Loffler expressly teach away from the claimed invention and the use of a

hydroalcoholic gel containing in excess of 50% w/w water. As a result, one of Singh, Singh & Roberts, Hong, Obata, and Loffler, either individually or combined, fail to teach all of the Applicant's claim features "as a whole," and therefore, fail to support a finding of obviousness. Applicant respectfully submits that the combination of Singh, Singh & Roberts, Hong, Obata, and Loffler do not render obvious Claims 7-11, 14-24, 26-29, and 38 , which ultimately depend from Claim 1. As a result, Applicant respectfully requests the Examiner to withdraw this rejection.

6. Rejection of Claims 30-37 and 49-52 under 35 U.S.C. § 103(a)

The Examiner rejected Claims 30-37 and 49-52 under 35 U.S.C. § 103(a) as allegedly being unpatentable over Singh, Singh & Roberts, Hong, Obata, and Loffler, and further in view of U.S. Patent Publication No. 2002/0172719 to Murad ("Murad"). Claims 30-37 and 49-52 ultimately depend from, and include every element of, Claim 1. Thus, Claims 30-37 and 49-52 have been clarified to recite a limitation that the hydroalcoholic gel dispersion comprises water in excess of 50% w/w. For at least the reasons discussed above, Singh, Singh & Roberts, Hong, Obata, and Loffler, either individually or combined, do not teach or suggest a hydroalcoholic gel dispersion comprising salicylic acid or a salt thereof where the amount of water in the composition is in excess of 50% w/w. In fact, Hong, Obata, and Loffler expressly teach away from the claimed invention and the use of a hydroalcoholic gel containing in excess of 50% w/w water. The teachings of Murad fail to supplement the deficiencies of Singh, Singh & Roberts, Hong, Obata, and Loffler, as Murad does not provide a teaching of a hydroalcoholic gel dispersion comprising salicylic acid or a salt thereof where the amount of water in the composition is in excess of 50% w/w. Thus, Applicant submits that Singh, Singh & Roberts, Hong, Obata, Loffler, and Murad do not set forth each and every element of the currently clarified claims. As a result, one of Singh, Singh & Roberts, Hong, Obata, Loffler, and Murad, either individually or combined, fail to teach all of the Applicant's claim features "as a whole," and therefore, fail to support a finding of obviousness. Applicant respectfully submits that the combination of Singh, Singh & Roberts, Hong, Obata, Loffler, and Murad do not render obvious Claims 30-37 and 49-52, which ultimately depend from Claim 1. As a result, Applicant respectfully requests the Examiner to withdraw this rejection.

7. Fees

This *Response and Amendment* is being filed as Applicant's submission accompanying a *Request for Continued Examination* along with a fee of $810. This *Response and Amendment* is being filed within six months of the *Office Action*, and more specifically within five months of the *Office Action*. As a result, Applicant submits herewith a petition for a two month extension of time fee of $490.

No additional claim fees are believed due, as the pending total claim count and number of independent claims remains covered under the original filing fee.

Authorization is hereby expressly given to the Commissioner to charge $1300 and any other fees that may be required or to credit any overpayment to Deposit Account No. 20-1507.

CONCLUSION

By the present *Response and Amendment*, this *Application* has been placed in full condition for allowance. Accordingly, Applicant respectfully request early and favorable action. Should the Examiner have any further questions or reservation, the Examiner is invited to telephone the undersigned attorney at 404.885.3038.

Respectfully submitted,

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